K122821

8.0 510(K) SUMMARY

DEC 13 2012

Submitter's Name	Veridex, LLC
Address	1001 US Highway 202 Raritan, NJ 08869-0606
Telephone Number **Fax Number**	908-927-4947 908-526-5059
Contact Person	Kimberly Prescott, Associate Director, Global Regulatory Affairs
Date:	December 6, 2012
Name of the Device	CELLTRACKS® AUTOPREP® System
Common or Usual Name	Automated Blood Cell Diluting Apparatus
Classification Name	Name: Immunomagnetic circulating cancer cell selection and enumeration system Device Class: II Product Code: NQI Regulation Number: 21 CFR 866.6020
Performance Standards	There are no performance standards promulgated for this device.
Indications for Use	The CELLTRACKS® AUTOPREP® System is a laboratory instrument used with immunomagnetic reagents that capture and enrich target cells, and labeling reagents that differentiate cells in whole blood. The CELLTRACKS ANALYZER II® may be used for cell identification and enumeration. The system is for in vitro diagnostic use.
Identification of the Legally Marketed Device (Predicate Device)	CELLTRACKS® AUTOPREP® System Name: Immunomagnetic circulating cancer cell selection and enumeration system Device Class: II Product Code: NQI Regulation Number: 21 CFR 866.6020

Device Description	The CELLTRACKS® AUTOPREP® System is a general purpose laboratory instrument used with immunomagnetic reagents that capture and enrich target cells, and labeling reagents that differentiate cells in whole blood. The CELLTRACKS® AUTOPREP® System processes up to 8 samples in a batch, performing all required process steps, including red cell detection, plasma aspiration and final transfer to the analysis cartridge. The user is prompted to perform various pre-processing operations such as dilution and centrifugation. Cell analyzers such as the CELLTRACKS ANALYZER II® may be used for cell identification and enumeration following processing. The CELLTRACKS® AUTOPREP® system uses a series of immunomagnetic separation procedures to isolate the cells of interest and to stain the cells with fluorescence-labeled monoclonal antibodies.
Comparison to Predicate Device	The CELLTRACKS® AUTOPREP® System (modified) is substantially equivalent to the CELLTRACKS® AUTOPREP® System (current - K110406, January 20, 2012). There has been no change to intended use, fundamental scientific technology, mode of operations, or specimen type/identification. The only change from the predicate device and subject of this Special 510(k) is a modification to the pipetting probe to reduce the potential for carryover, and a label change to the CELLTRACKS® AUTOPREP® System labeling to change the caution about carryover from circulating tumor cell (CTC) samples when containing 5,000 CTCs or greater per 7.5mL of blood.
Description of Testing	Non-clinical testing for the CELLTRACKS® AUTOPREP® System functional testing included: • New reagent probe versus current reagent probe assay performance equivalence • CTC (circulating tumor cell) spike level characterization of the new probe (tumor cell carryover and control cell carryover) • Run to Run carryover characterization • Reliability/Life testing

Conclusion of Testing	The information presented in the premarket notification demonstrates that the performance of the CELLTRACKS® AUTOPREP® System (modified) is substantially equivalent to the predicate device. Equivalence was demonstrated through non-clinical functional testing for the modified device. The information presented in the premarket notification provides a reasonable assurance that the CELLTRACKS® AUTOPREP® System (modified) is as safe and effective as the predicate device for the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Letter Date: December 13, 2012

Veridex, LLC
C/O Ms. Kimberly Prescott
1001 US Highway 202
Raritan, NJ 08869-1424

Re: 510(k) Number:	k122821
Trade/Device Name:	CELLTRACKS AUTOPREP® System
Regulation Number:	21 CFR 866.6020
Regulation Name:	Immunomagnetic circulating cancer cell selection and enumeration system
Regulatory Class:	Class II
Product Code:	NQI
Dated:	November 8, 2012
Received:	November 9, 2012

Dear Ms. Prescott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Reena Philip -S

for Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122821

Device Name: CELLTRACKS® AUTOPREP® System

Indications for Use:

The CELLTRACKS® AUTOPREP® System is a laboratory instrument used with immunomagnetic reagents that capture and enrich target cells, and labeling reagents that differentiate cells in whole blood. The CELLTRACKS ANALYZER II® may be used for cell identification and enumeration. The system is for in vitro diagnostic use.

Prescription Use ___X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510K K122821